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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,329	08/21/2001	Luc Desgroseillers	163-34	8479

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EXAMINER	
PAK, YONG D	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/913,329	DESGROSEILLERS ET AL.	
	Examiner	Art Unit	
	Yong D Pak	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 February 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13,15-28 and 30-61* is/are pending in the application.

4a) Of the above claim(s) *1-5, 7-13, 15-28, 30-38, 44-46 and 50-55* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6, 39-40 and 56-61* is/are rejected.

7)☒ Claim(s) *41-43 and 47-49* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed on February 23, 2004, amending claims 6 and 40, canceling claims 14 and 29 and adding claims 41-61.

Claims 1-13, 15-28 and 30-61 are pending.

Election/Restrictions

Claims 1-5, 7-13, 15-28, 30-38, 44-46 and 50-55 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 16.

Claim Objections

Claims 6 and 39-40 are objected for being drawn to non-elected products, SEQ ID NOs: 14 and 15.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6, 39-40 and 56-61 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Newly amended claims 6 and 39-40 and newly submitted claims 56-58 are drawn to a nucleotide sequence comprising a nucleotide sequence encoding amino acids 1-63 of SEQ ID NO:13. Newly amended claims 6 and 39-40 and newly submitted claims 59-61 are drawn to a nucleotide sequence comprising a nucleotide sequence encoding an N-terminal fragment of any metallopeptidase and nucleotides 332-520 of SEQ ID NO:12. Applicants argue that support for these newly amended claims and newly submitted claims are found, for example, at page 10, lines 12-13 of the specification (Remarks, page 13, 2nd paragraph). However, page 10 of the specification nor the specification in its entirety describe nucleotide sequences comprising of said fragments.

Response to Arguments

Applicant's arguments filed on February 23, 2004, with respect to claims 6 and 39-40 under 35 U.S.C. 112, 2nd paragraph have been fully considered and are persuasive. The rejection of claims 6 and 39-40 under 35 U.S.C. 112, 2nd paragraph has been withdrawn.

Applicant's arguments filed on February 23, 2004, with respect to claims 6 and 39 under 35 U.S.C. 102(b) of the Marra et al. reference have been fully considered and are persuasive. The rejection of claims 6 and 39 under 35 U.S.C. 102(b) has been withdrawn.

Applicant's arguments filed on February 23, 2004, with respect to claim 29 under 35 U.S.C. 102(b) of the Bandman et al. reference have been fully considered and are persuasive.

The rejection of claim 29under 35 U.S.C. 102(b) has been withdrawn. Applicant's arguments with respect to claims 14 and 29 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6, 39-40 and 56-61 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 6, 39-40 and 56-58 are drawn to a nucleotide sequence comprising a nucleotide sequence encoding an N-terminal fragment of a metallopeptidase constituted of amino acids 1 to 63 of SEQ ID NO:13. Therefore, the claims are drawn to a large variable genus of polynucleotides encoding polypeptides having unknown activity or inactive variants and having unlimited structure. The specification does not describe the

function of the fragment composed of amino acids 1-63 of SEQ ID NO:13. The specification does not describe the function of all the polypeptide sequences comprising amino acids 1 to 63 of SEQ ID NO:13 and therefore, many functionally unrelated polynucleotides are encompassed within the scope of these claims. Therefore, applicants fail to describe representative species by identifying functional properties.

Claims 6, 39-40 and 59-61 are drawn to a nucleotide sequence comprising a nucleotide sequence encoding an N-terminal fragment of any metallopeptidase and having nucleotides 332-520 of SEQ ID NO:12. Therefore, the claims are drawn to a large variable genus of polynucleotides encoding polypeptides having unknown activity or inactive variants and having unlimited structure. The specification does not describe any structural characteristics of this fragment, such as its length. The specification also does not describe the function of the fragment encoded by nucleotides 332-520 of SEQ ID NO:13. The specification also does not describe N-terminal fragments of any metallopeptidase. Therefore, many functionally and structurally unrelated polynucleotides are encompassed within the scope of these claims. Therefore, applicants fail to describe representative species by identifying functional or structural properties other than comprising of nucleotides 332-520 of SEQ ID NO:12.

Given this lack of description of the representative species encompassed by the genus of the claims, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the inventions of claims 6, 39-40 and 56-61.

Claims 6, 39-40 and 56-61 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the polynucleotides encoding the NEP protein of SEQ ID NO:13 and host cell comprising said polynucleotide, does not reasonably provide enablement polynucleotides encoding a polypeptide having unknown function and unlimited structure. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required are summarized in In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The claims are drawn to polynucleotides encoding polypeptides having unknown function. The claims broadly encompass not only metallopeptidase polynucleotides, but any polynucleotides comprising of fragments of polynucleotides encoding SEQ ID NO:13. The claims also encompass molecules having very low structural similarity to the polynucleotide encoding SEQ ID NO:13 that exhibit metallopeptidase activity and proteins of unknown functionality. Therefore, these claims encompass polynucleotides encoding a metallopeptidase having structures with low homology to SEQ ID NO:13.

Therefore, the breadth of these claims is much larger than the scope enable by the specification.

The claims area also drawn to polynucleotides comprising an N-terminal fragment of any metallopeptidase and a portion of SEQ ID NO:12. The specification does not teach any structural characteristics of the N-terminal fragment, such as its length. The family of metallopeptidase is a very large and complex one. Despite knowledge in the art for the isolation of amino acids, the specification fails to provide guidance regarding how to isolate other metallopeptidase whose sequence is different to SEQ ID NO:13. Therefore, the breadth of these claims is much larger than the scope enable by the specification.

The predictability as to the level of conservation between the disclosed sequences and those of other metallopeptidase is extremely complex. While recombinant techniques are available, it is not routine in the art to screen large numbers of amino acids where the expectation of obtaining similar sequences is unpredictable. The amino acid sequence determines the structural and functional properties of an enzyme. Knowledge of which sequences can be altered or removed and still result in similar protein activity is well outside the realm of routine experimentation.

The quantity of experimentation in this area is extremely large since there is significant variability in the structure of all metallopeptidase. It would require significant study to identify an N-terminal fragment of any metallopeptidase and would be an inventive, unpredictable and difficult undertaking. This would require years of inventive

effort, with each of the many intervening steps, upon effective reduction to practice, not providing any guarantee of success in the succeeding steps.

Further, the specification does teach how to make variants of polynucleotides encoding SEQ ID NO:13. However, the function of a polypeptide cannot be predicted from its structure and the specification does not teach how to use polypeptides with unknown function. The quantity of experimentation in this area is extremely large since there is significant variability in the activity of the polynucleotides in the claims. It would require significant study to identify the actual function of the encoded polypeptides and identifying a use for the polypeptide would be an inventive, unpredictable and difficult undertaking. This would require years of inventive effort, with each of the many intervening steps, upon effective reduction to practice, not providing any guarantee of success in the succeeding steps.

The art is extremely unpredictable with regard to protein function in the absence of realizable information regarding its activity. Even very similar proteins may have every different functions. In the current case, where no specific information is know regarding the function, it is entirely unpredictable what function and activity will be found for the protein. The prior art does not resolve this ambiguity, since no prior art activity is identified for the encoded polypeptides.

Therefore, one of ordinary skill would require guidance in order to use polynucleotides encoding polypeptides having unknown function in a manner reasonable correlated with the scope of the claims. Without such guidance, the experimentation left to those skilled in the art is undue.

Allowable Subject Matter

Claims 41-43 and 47-49 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

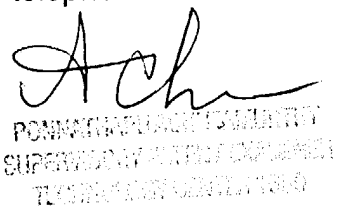
Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 703-308-9363. The examiner can normally be reached 6:30 A.M. to 5:00 P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Yong D. Pak
Patent Examiner

May 12, 2004